11-sc-1433 DSD/JJG

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA
Civil No.11-SM-39 (DSD/JJG)

UNITED STATES OF AMERICA,

Plaintiff,

v.

39 cases, more or less, each case containing 72/100 capsule plastic bottles of an article of drug labeled in part:

(case and bottle)

"*** DDS *** PROBIOTICS *** DDS®-100 (or "DDS® Plus," or "Probioplus DDS®") *** *L. acidophilus DDS-1* *** 100 VEG. CAPS *** UAS LABORATORIES *** Eden Prairie, MN ***"

and

5 cases, more or less, each case containing 72/2.5 ounce plastic bottles of powder, an article of drug, labeled in part:

(case and bottle)

"*** DDS *** PROBIOTICS *** DDS® *** Acidophilus *** *L. acidophilus DDS-1* *** 2.5 oz. POWDER *** UAS LABORATORIES *** Eden Prairie, MN ***"

and

15 cases, more or less, each case containing 72/2.5 ounce plastic bottles of powder, an article of drug, labeled in part:

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COMPLAINT FOR FORFEITURE

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(case and bottle)

"*** DDS *** PROBIOTICS *** DDS® Plus (or "DDS® Junior")*** *L. acidophilus DDS-1* *** 2.5 oz. POWDER *** UAS LABORATORIES *** Eden Prairie, MN ***"

and

6 cases, more or less, each case containing 72/100 tablet plastic bottles of an article of drug labeled in part:

(case and bottle)

"*** DDS *** PROBIOTICS *** DDS® *** Acidophilus *** *L. acidophilus DDS-1* *** 100 TABLETS *** UAS LABORATORIES *** Eden Prairie, MN ***"

and

17 cases, more or less, each case containing 72/60 capsule plastic bottles of an article of drug labeled in part:

(case and bottle)

"*** CRAN-GYN DDS® *** *DDS®-Probiotics* *** 60 VEGETARIAN CAPSULES *** UAS LABORATORIES *** Eden Prairie, MN ***"

and

all other articles of drug, in any form (capsules, powder, or tablets), and in any size and type container, which are labeled or otherwise identified as DDS Probiotics, located on the premises of UAS Laboratories, Inc., 9953 Valley View Road, Eden Prairie, Minnesota,

)
Defendants.)

VERIFIED COMPLAINT FOR FORFEITURE IN REM

NOW COMES the United States of America, by its attorney B. Todd Jones, United States Attorney for the District of Minnesota, and Ana H. Voss, Assistant United States Attorney for said District, who respectfully state as follow:

NATURE OF THE ACTION

1. That this complaint is filed by the United States of America, and requests seizure and condemnation of articles of drugs as described in the caption (the "defendant articles"), in accordance with the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 301 *et seq*.

2. There are held at Eden Prairie, Minnesota, in the possession of UAS Laboratories, Inc., or elsewhere within the jurisdiction of this Court, the defendant articles of drug that were shipped in interstate commerce from outside the State of Minnesota, specifically, from Wausau, Wisconsin.

JURISDICTION AND VENUE

3. Plaintiff brings this action in rem in its own right to condemn and forfeit the defendant articles. This Court has jurisdiction over an action commenced by the United States under 28 U.S.C. § 1345 and 21 U.S.C. § 334, which provides this Court with jurisdiction over seizures brought under the Act.

4. This Court has *in rem* jurisdiction over the defendant articles because they are located in the District of Minnesota. Upon the filing of this complaint, the United States

requests that this Court issue an arrest warrant *in rem* pursuant to Rule G(3)(b) of the Supplemental Rules for Admiralty or Maritime Claims and Asset Forfeiture Actions (the "Supplemental Rules"), Federal Rules of Civil Procedure, which the United States will execute upon the defendant articles pursuant to Rule G(3) of the Supplemental Rules.

BASIS FOR FORFEITURE

5. The defendant articles are drugs within the meaning of the Act, 21 U.S.C. § 321(g)(1), in that they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.

6. The defendant articles are also "new drugs" within the meaning of 21 U.S.C. § 321(p), because they are not generally recognized by qualified experts as safe and effective for their recommended uses. Among other things, the defendant articles are intended to prevent or treat colds, flu, respiratory infections, urinary tract infections, yeast infections, ulcers, and to lower cholesterol. No approval of an application filed pursuant to 21 U.S.C. § 355(b), or exemption from such requirement, pursuant to 21 U.S.C. § 355(i), is in effect for such drugs. The defendant articles may not be introduced into interstate commerce pursuant to 21 U.S.C. § 355 and are thus subject to seizure under 21 U.S.C. § 334.

7. The defendant articles are misbranded while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of 21 U.S.C. § 352(f)(1), in that their labeling fails to bear adequate directions for use, and they are not

exempt from such requirement under 21 C.F.R. § 201.115, because the defendant articles are unapproved new drugs.

8. By reason of the foregoing, the defendant articles are held illegally within the jurisdiction of this Court and are liable to seizure and condemnation pursuant to 21 U.S.C. § 334.

FACTS

9. UAS Laboratories, Inc. is a distributor of various types of probiotic products. Although it refers to these products as dietary supplements, UAS Laboratories Inc. makes claims on its website, www.uaslabs.com, that its products treat and prevent the various disease conditions set out in paragraph 6. The company's website provides a phone number for consumers to order the products and includes a direct link to a website, www.wholeapproach.com, from which the products may be purchased directly and which also contains similar disease claims.

10. In a Warning Letter issued on May 13, 2005, the Food and Drug Administration ("FDA") warned UAS Laboratories, Inc. that claims on its product labeling, including www.uaslabs.com, relating to the treatment or prevention of such conditions as yeast infections, ulcers, and high cholesterol caused the products to be drugs within the meaning of the Act, 21 U.S.C. § 321(g). The Warning Letter also explained that UAS Laboratories, Inc's probiotic products were not generally recognized as safe and effective when used as labeled, and therefore, were also new drugs within the meaning of Act, 21

U.S.C. § 321(p). During a meeting with FDA on June 16, 2005, UAS Laboratories, Inc. promised to fully correct its violations.

11. FDA conducted a follow-up inspection of UAS Laboratories, Inc. between September 11 and September 19, 2007, at which time FDA confirmed that the company had removed the disease claims that led to the May 2005 Warning Letter from its product labeling. Since September 2007, FDA conducted two inspections of UAS Laboratories, Inc. During the most recent inspection conducted between March 9 and 15, 2011, the FDA investigator discovered that UAS Laboratories, Inc. continued to make claims on its website that its products treat and prevent various disease conditions. At the close of the March 2011 inspection, the FDA investigator discussed the content of www.uaslabs.com and its link to www.wholeapproach.com, warned the company about the violations, and noted that the disease claims on the websites were very similar to the claims that were cited in the 2005 Warning Letter. An FDA review of www.uaslabs.com and www.wholeapproach.com as of May 14, 2011, found that UAS Laboratories, Inc. was making the same or similar disease claims – including claims that the defendant articles treat or prevent colds, flu, respiratory infections, urinary tract infections, yeast infections, ulcers, and high cholesterol. Despite the company's 2005 promise to fully remove the claims from its website and FDA's repeated warnings, UAS Laboratories, Inc. continues to market the misbranded defendant articles.

WHEREFORE, the United States of America prays that a warrant for arrest *in rem* for the defendant articles of drug located within the District of Minnesota be issued; that due

notice be given to all parties to appear and show cause why the seizure and condemnation should not be decreed; that the judgment be entered declaring the defendant articles of drug be condemned and disposed of according to law; and that the United States of America be granted such other and further relief as this Court may deem just and proper, together with cost and disbursement of this action.

Dated this 1st day of June, 2011.

Respectfully submitted,

Of Counsel:

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Acting General Counsel

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VERIFICATION

STATE OF MINNESOTA :
: ss
COUNTY OF HENNEPIN :

Tyra S. Wisecup, of full age, being duly sworn according to law, upon her oath deposes and says:

1. I am a Compliance Officer of the United States Food and Drug Administration and as such am presently assigned to the above-captioned matter.

2. The allegations contained in the attached Complaint are true to the best of my knowledge, information, and belief.

TYRA S. WISECUP

Sworn and subscribed to
before me this 24th day
of May, 2011, at
Minneapolis, Minnesota

May 24, 2011

ANGELA M NYKANEN
NOTARY PUBLIC
MINNESOTA
MY COMMISSION EXPIRES
JANUARY 31, 2016